

Attorney Docket No. 6197.214-US
Kanstrup et al.
Serial No. 10/621,302 Filed July 17, 2003
Via Fax No.: 703-872-9306

RESPONSE

The examiner states in the Office Action Summary that claims numbered 1-54 are pending in the application; claims numbered 1-54 are rejected. Applicant respectfully submits claims numbered 1-2 are pending in the present application.

The rejections of Claim 1 under 35 U.S.C. §102(b) and §103(a) over Klinger (US Patent No. 3,896,119) have been obviated by appropriate amendment.

The Office Action states that species (a)-(c), listed below, have been "placed in the public domain" by Klinger and thus anticipate and obviate Claim 1 of the above-identified application.

- (a) 7-(3-Chloro-propyl)-1,3-dimethyl-8-piperazin-1-yl-3,7-dihydro-purine-2,6-dione;
- (b) 7-(3-Amino-propyl)-1,3-dimethyl-8-piperazin-1-yl-3,7-dihydro-purine-2,6-dione; and,
- (c) 3-(1,3-Dimethyl-2,6-dioxo-8-piperazin-1-yl-1,2,3,6-tetrahydro-purin-7-yl)-propionaldehyde;

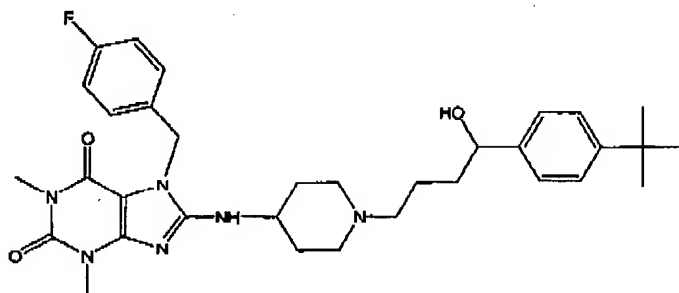
Applicants have now removed these three species from Claim 1 via proviso. Since the Office Action acknowledges that species (a)-(c) are intermediates; there is no motivation to modify intermediates except to make their intended final product; and, the intended final products (i.e., the species of Column 2, lines 26-28) have not been alleged to anticipate or obviate Claim 1; Applicants submit that Klinger does not anticipate or obviate Claim 1, as amended.

Withdrawal of these rejections under 35 U.S.C. §102(b) and §103(a) is respectfully requested.

The rejection of Claims 1-2 under 35 U.S.C. §102(b) over Bonnet (US Patent No. 5,461,059) is respectfully traversed.

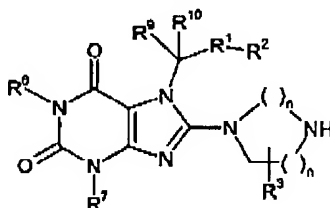
Example I of Bonnet has been alleged to anticipate Claims 1-2. Example I describes the preparation of a Xanthine of formula I_A". Example I appears to be the following compound.

Attorney Docket No. 6197.214-US
 Kanstrup et al.
 Serial No. 10/621,302 Filed July 17, 2003
 Via Fax No.: 703-872-9306



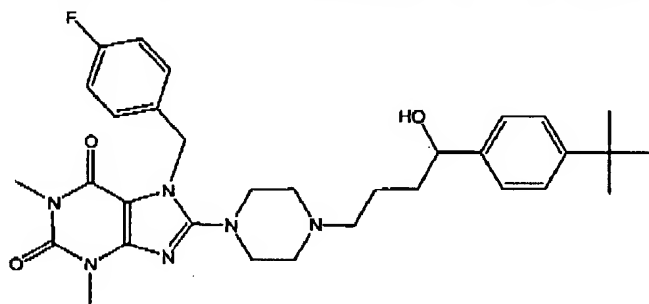
Example I of Bonnet

Example I of Bonnet cannot anticipate the presently claimed invention since the presently claimed formula I, shown below, recites a ring attached via a nitrogen to the central imidazole, and Example I of Bonnet doesn't have this feature.



I

It is likely that Example II of Bonnet was intended, not Example I. Example II of Bonnet is shown below. It does have a ring attached to the central imidazole via a nitrogen atom.



Example II of Bonnet

Applicants submit that Example II of Bonnet does anticipate the presently claimed invention due to the terminal t-butyl-phenyl group of Example II. Applicants further submit that the generic description in Bonnet cannot anticipate the presently claimed invention due to the required phenyl-R₇ group. Bonnet requires an R₆-butylene group attached to a piperazine and terminated by a phenyl-CO₂H, phenyl-t-butyl, or a phenyl-C(CH₃)₂CO₂H. While Applicants noted that the presently recited diaza-ring-R³ group covers an R⁸-substituted phenyl-alkylene-

Attorney Docket No. 6197.214-US
Kanstrup et al.
Serial No. 10/621,302 Filed July 17, 2003
Via Fax No.: 703-872-9306

pipazine moiety, R^8 , as amended, does not cover the required CO_2H , t-butyl, or a $C(CH_3)_2CO_2H$ substituent. As a result, withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

The rejection of Claims 1-2 under 35 U.S.C. §112, 2nd paragraph, has been obviated in part and is respectfully traversed in part. The numbering of the following response paragraphs corresponds to the numbering of the paragraphs in the Office Action mailed February 18, 2004.

(1): The third species has been removed.

(2): $-OPO_3H$ has been replaced with $-OPO_3H_2$. Applicants submit that one of ordinary skill in the art would recognize that a hydrogen atom was missing. If an oxygen atom were removed, then it would leave a tetravalent phosphorous. Thus, the error is obviously the absence of an oxygen. This addition is also supported by the third choice on page 118, line 11 (i.e., $-PO_3H_2$).

(3): $-OPO_2OCH_3$ has been replaced with $-OPO(OH)(OCH_3)$. Like with Part 2, the only option to make a pentavalent phosphorous is the addition of a hydrogen. This addition is also supported by the last group in the same line (i.e., $-PO(OH)(OCH_3)$).

(4): $-C(OCH_3)_2$ has been replaced with $-CH(OCH_3)_2$. Applicants submit that one of ordinary skill in the art would recognize that $-C(OCH_3)_2$ was intended to represent a dimethoxy-protected aldehyde, except that a simple clerical error was made and the hydrogen was left off. Its position next to $-CHO$ provides additional support for this correction.

(5): Applicants respectfully disagree that the R^1 choices must be divalent. If R^2 is H, then R^1 could represent an alkyl group instead of an alkylene group. Applicants submit that one of ordinary skill in the art would recognize that at least some of the groups recited for R^1 (e.g., alkyl) could be mono- or divalent. Applicants further submit that one of ordinary skill in the art would recognize that an alkyl group could also be an alkylene group if R^2 were other than hydrogen.

(6): The "preferably" language in R^4 has been replaced with "selected from" language.

(7): The requested changes have been made in R^4 and in R^9/R^{10} .

Attorney Docket No. 6197.214-US
Kanstrup et al.
Serial No. 10/621,302 Filed July 17, 2003
Via Fax No.: 703-872-9306

(8): The spelling error has been corrected.

(9): Applicants do not understand this rejection. Is it the last line on page 117 or line 13. Either way, if this rejection is maintained, then Applicants request further clarification of what language is being rejected.

(10): The formatting of R⁵ has been made consistent.

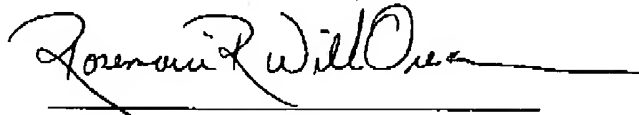
Withdrawal of the §112, 2nd paragraph rejection is now respectfully requested.

The objection to the Abstract has been obviated by appropriate amendment. Applicants have replaced the Abstract with one that recites formula I. Due to the length of the definitions for R¹ and R², Applicants have not included these two definitions in the abstract. Withdrawal of this objection to the specification is respectfully requested.

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Date: August 18, 2004



Rosemarie R. Wilk-Orescan
Registration Number 45,220
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5969

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE